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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/765,625	01/26/2004	Michael Bensen	A04P1009	2274

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PACESETTER, INC.
15900 VALLEY VIEW COURT
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EXAMINER	
WU, EUGENE TONG	
ART UNIT	**PAPER NUMBER**
3766	
MAIL DATE	**DELIVERY MODE**
07/11/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/765,625	BENSER ET AL.	
	Examiner	Art Unit	
	Eugene T. Wu	3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 May 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9,12-17,20-29 and 31* is/are rejected.

7)☒ Claim(s) *10,11,18,19 and 30* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *26 January 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *01/26/04, 05/10/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Invention I, claims 1-31, in the reply filed on 05/04/2007 is acknowledged.

Oath/Declaration

2. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

It does not state that the person making the oath or declaration acknowledges the duty to disclose to the Office all information known to the person to be material to patentability as defined in 37 CFR 1.56.

In particular, the correct statement should read, "I acknowledge the duty to disclose information which is **material to patentability** of this application in accordance with Title 37, Code of Federal Regulations Section 1.56." (emphasis added).

Specification

3. The disclosure is objected to because of the following informalities:

a. Paragraph 1: Please provide the application serial number for the related case.

Appropriate correction is required.

Claim Objections

4. Claims 7, 10 objected to because of the following informalities:

a. Claim 7: "IEGM" should be written in non-abbreviated form.

b. Claim 10: "the decrease in tidal volume" lacks antecedent basis in the claims.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

5. Claim 17 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In particular, it is unclear what is the "most recent" respiratory information? What is the time frame that consists of the "most recent" information? The last few breaths? Last few minutes? Last few days?

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. In light of the 112 rejection above, the Office is interpreting "most recent" respiratory information to include the last few breaths.

8. Claims 1-4, 6-9, 12, 14, 16, 17, 20-28 rejected under 35 U.S.C. 102(e) as being anticipated by Tehrani (US 2005/0085865). In claims 8 and 9, the "intends to..." clause has been carefully considered but deemed not to add further limitations to the claims, since increasing tidal volume is an intended outcome, rather than a recited step.

Regarding claims 1, 8, 9, 12, 16, and 20, Tehrani discloses the same invention substantially as claimed, including sensing respiratory information related to tidal volume (Paragraphs 11, 12, 41), a

microprocessor determining if the tidal volume is less than a limit 400 (Figures 6, 9C; Paragraphs 16, 71, 73), and calling for diaphragm activation based on a nonincreasing monotonic relationship (Figure 9C; Paragraphs 71, 73).

Regarding claim 2, Tehrani discloses phrenic or diaphragmic activation (abstract).

Regarding claim 3, Tehrani discloses delivering diaphragmic activation 403 (Figure 9C).

Regarding claim 4, Tehrani discloses delivering diaphragm activation during inspiration (Figures 10A/B; Paragraph 58).

Regarding claim 6 and 23, Tehrani discloses the limit relies on historical respiratory information based on normal breathing patterns and unaffected by CSR (Figure 9C; Paragraphs 63, 73).

Regarding claims 7 and 22, Tehrani discloses neural activity information (Paragraph 12).

Regarding claim 14, Tehrani discloses determining stimulation power based on error 406 (Figure 9C).

Regarding claim 17, Tehrani discloses the error relying on the most recent respiratory information (Figure 9C). Since the error is a measure between the current breath and a historical breath limit, the error includes the most recent respiratory information.

Regarding claim 21, Tehrani discloses a connector (Figures 1-6).

Regarding claim 24, Tehrani discloses a pulse generator (Figures 1-6).

Regarding claim 25, Tehrani discloses an output (Figures 1-6).

Regarding claim 26, Tehrani discloses a connector (Figures 1-6).

Regarding claims 27 and 28, Tehrani discloses a pulse generator and a lead (Figures 1-6; abstract).

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 5, 13, 15, and 29 rejected under 35 U.S.C. 103(a) as being unpatentable over Tehrani (US 2005/0085865) as applied to claims 1, 12, 16, and 20, and further in view of Meer (US 4,830,008).

Regarding claim 5, Tehrani as applied to claim 3 is described above. Tehrani does not disclose monitoring upper airway patency. However, Meer teaches monitoring upper airway patency (abstract), in order to prevent upper airway collapse. Therefore, it would have been obvious to one with ordinary skill in the art at the time the invention was made to include the monitoring upper airway patency of Meer with the invention of Tehrani, in order to prevent upper airway collapse.

Regarding claim 13, Tehrani further discloses delivering the diaphragm activation 403 (Figure 9C). Tehrani does not disclose determining whether an airway collapse occurred. However, Meer teaches monitoring upper airway patency (abstract), in order to prevent upper airway collapse. Therefore, it would have been obvious to one with ordinary skill in the art at the time the invention was made to include the monitoring upper airway patency of Meer with the invention of Tehrani, in order to prevent upper airway collapse.

Regarding claim 15, Tehrani further discloses determining stimulation power based on error 406 (Figure 9C) and delivering diaphragmic activation 403. Tehrani does not disclose determining whether an airway collapse occurred. However, Meer teaches monitoring upper airway patency (abstract), in order to prevent upper airway collapse. Therefore, it would have been obvious to one with ordinary skill in the art at the time the invention was made to include the monitoring upper airway patency of Meer with the invention of Tehrani, in order to prevent upper airway collapse.

Regarding claim 29, Tehrani as applied to claim 20 is described above. Tehrani does not disclose determining whether an airway collapse occurred. However, Meer teaches monitoring upper airway patency (abstract), in order to prevent upper airway collapse. Therefore, it would have been obvious to one with ordinary skill in the art at the time the invention was made to include the monitoring upper airway patency of Meer with the invention of Tehrani, in order to prevent upper airway collapse.

12. Claims 1-3, 6-9, 12, 14, 16, 17, 20-28, 31 rejected under 35 U.S.C. 103(a) as being unpatentable over Scheiner (US 6,415,183) in view of Kallok (US 5,211,173).

Regarding claims 1, 8, 9, 12, 14, 16, 17, and 20, Scheiner discloses the same invention substantially as claimed, including sensing minute ventilation (abstract), which is related to tidal

volume (Col. 5, lines 47-48), a microprocessor determining if the tidal volume is less than a limit (Figure 2; Col. 6, lines 19-21), and calling for diaphragm activation (abstract; Col. 6, lines 19-21). Scheiner does not disclose a stimulation power based on a nonincreasing monotonic relationship. However, Kallok teaches adjusting stimulation power based on a nonincreasing monotonic relationship with respect to increasing respiratory information, based on most recent respiratory information (Col. 1, line 58 to Col. 2, line 8), in order to reduce muscle fatigue and overstimulation (Col. 2, lines 9-17). Therefore, it would have been obvious to one with ordinary skill in the art at the time the invention was made to modify the invention of Scheiner to include the adjusting stimulation power based on a nonincreasing monotonic relationship with respect to increasing respiratory information of Kallok, in order to reduce muscle fatigue and overstimulation.

Regarding claim 2, Scheiner further discloses phrenic nerve stimulation (abstract).

Regarding claim 3, Scheiner further discloses delivering activation (abstract).

Regarding claims 6 and 23, Scheiner further discloses the limit relies on historical respiratory information unaffected by CSR (Col. 5, lines 44-63; Col. 6, lines 57-65).

Regarding claims 7 and 22, Scheiner further discloses impedance information (Col. 5, lines 44-63).

Regarding claim 21, Scheiner further discloses a connector (Figure 1A).

Regarding claim 24, Scheiner further discloses a pulse generator (Figure 1A).

Regarding claim 25, Scheiner further discloses an output (Figure 1A).

Regarding claim 26, Scheiner further discloses a connector (Figure 1A).

Regarding claims 27 and 28, Scheiner further discloses a pulse generator and a lead (Figure 1A).

Regarding claim 31, Scheiner further discloses a cardiac stimulation output (Figure 1A; Col. 2, lines 10-27).

13. Claims 5, 13, 15, and 29 rejected under 35 U.S.C. 103(a) as being unpatentable over Scheiner (US 6,415,183) and Kallok (US 5,211,173) as applied to claims 1, 12, 16, and 20, and further in view of Meer (US 4,830,008).

Regarding claim 5, Scheiner and Kallok as applied to claim 3 is described above. Scheiner or Kallok does not disclose monitoring upper airway patency. However, Meer teaches monitoring upper airway patency (abstract), in order to prevent upper airway collapse. Therefore, it would have been obvious to one with ordinary skill in the art at the time the invention was made to include the monitoring upper airway patency of Meer with the modified invention of Scheiner and Kallok, in order to prevent upper airway collapse.

Regarding claim 13, Scheiner and Kallok further discloses delivering the diaphragm activation (Scheiner: abstract). Scheiner or Kallok does not disclose determining whether an airway collapse occurred. However, Meer teaches monitoring upper airway patency (abstract), in order to prevent upper airway collapse. Therefore, it would have been obvious to one with ordinary skill in the art at the time the invention was made to include the monitoring upper airway patency of Meer with the modified invention of Scheiner and Kallok, in order to prevent upper airway collapse.

Regarding claim 15, Scheiner and Kallok further disclose determining stimulation power based on error (Kallok: Col. 1, line 58 to Col. 2, line 8) and delivering diaphragmic activation (Scheiner: abstract). Scheiner or Kallok does not disclose determining whether an airway collapse occurred. However, Meer teaches monitoring upper airway patency (abstract), in order to prevent upper airway collapse. Therefore, it would have been obvious to one with ordinary skill in the art at

the time the invention was made to include the monitoring upper airway patency of Meer with the modified invention of Scheiner and Kallok, in order to prevent upper airway collapse.

Regarding claim 29, Scheiner and Kallok as applied to claim 20 is described above. Scheiner or Kallok does not disclose determining whether an airway collapse occurred. However, Meer teaches monitoring upper airway patency (abstract), in order to prevent upper airway collapse. Therefore, it would have been obvious to one with ordinary skill in the art at the time the invention was made to include the monitoring upper airway patency of Meer with the modified invention of Scheiner and Kallok, in order to prevent upper airway collapse.

Allowable Subject Matter

14. Claims 10 and 11 would be allowable if rewritten to overcome the claim objections set forth above, and to include all of the limitations of the base claim and any intervening claims.

15. Claims 18, 19, 30 objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

16. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

a. Ottenhoff (US 6,269,269) shows varying stimulation with respiratory effort.

b. Hansen (US 6,357,438) shows providing proportional respiratory assist.

c. Kallok (US 5,146,928) shows stimulating both the upper airway and diaphragm.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eugene T. Wu whose telephone number is (571) 272-3109. The examiner can normally be reached on M-F: 9 AM - 5 PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571)272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ETW
07/05/2007

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